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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/214,848 01/14/99 SEKINE

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EXAMINER

HM12/0313

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WASHINGTON DC 20006

WILLIAMS, P

ART UNIT

PAPER NUMBER

1616

DATE MAILED:

03/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Applicati n No.

09/214,848

Applicant(s)

SEKINE, TERUAKI

Examiner

Pernell V. Williams

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☒ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 17) ☐ Interview Summary (PTO-413) Paper No(s): ____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: _____.

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DETAILED ACTION

Claims 1-4 are pending and presented for examination.

Information Disclosure Statement

1. The information disclosure statement filed 14 January 1999 fails to fully comply with 37 CFR 1.98(a)(3), because reference AA on the modified PTO Form 1449 (filed 14 January 1999), referring to the Foreign Patent Document JP 3-80076 (4/91) is unaccompanied by a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for remedies or treatments, does not reasonably provide enablement for preventatives or prevention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

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connected, to make and use the inventions commensurate in scope with these claims. In the instant application, the disclosure is not seen to allow a person of ordinary skill in the art of antiviral therapy to make and use a composition which completely excludes a patient from contraction of any viral pathogen.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant application seeks to claim "remedies" which is indefinite, since a "remedy" can be read as a composition or a method. Compositions and methods may not be disclosed in the same claim, so appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,316,763 (Ochoa *et al.*), and further in view of US Patent 4,690,915 (Rosenberg).

Determining the scope and contents of the prior art

Ochoa *et al.* discloses that T cells cultured in the presence of both Interleukin 2 (IL-2) and monoclonal antibodies directed against the CD-3 receptor complex (anti-CD3

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MoAb) do produce stimulated T lymphocytes with Lymphokine Activated Killer cell characteristics. Ochoa *et al.* also discloses that the incubation with IL-2 is a viable alternative to injecting IL-2 into the patient. See column 1 lines 34-51, column 2 lines 36-36, and column 3 lines 46-60.

Ascertaining the differences between the prior art and the claims at issue

The instant application claims as essential that the lymphocytes cultured in the presence of IL-2 and antiCD3 MoAb be autologous from an immunologically depressed patient, and effective against viral components.

Resolving the level of ordinary skill in the pertinent art

The Rosenberg patent discloses that IL-2-activated lymphocytes are preferred to be used to treat immunologically dysfunctional patients with viral or other infective diseases. The instant application, Ochoa *et al.*, and Rosenberg are seen to be in the art of adoptive immunotherapy. In light of Rosenberg, it would have been obvious to the practitioner of ordinary skill in this art at the time the invention was made to expect the autologous lymphocytes cultured in the presence of IL-2 and antiCD3 MoAb as disclosed by Ochoa *et al.* be efficacious in treating viral infections in immunologically dysfunctional patients.

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Considering objective evidence present in the application indicating obviousness or nonobviousness

It is noted that there has not been presented any evidence of record to obviate the rejection cited *supra*. The disclosures of the components as set forth in the prior art patents are seen to render the instantly claimed composition *prima facie* obvious. Hence, there is no evidence in the present application to support nonobviousness.

Conclusion

Claims 1-4 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pernell V. Williams, whose telephone number is (703) 308-4645. The examiner can normally be reached from 8AM to 4:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached at (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

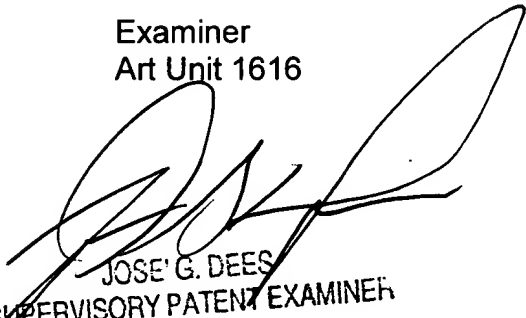
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



pvw
March 10, 2000

Examiner
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JOSE G. DEES
SUPERVISORY PATENT EXAMINER

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